

UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF ILLINOIS

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IN RE YASMIN AND YAZ 3:09-MD-02100-DRH-CJP  
(DROSPIRENONE) MARKETING, SALES  
PRACTICES AND RELEVANT PRODUCTS MDL 2100  
LIABILITY LITIGATION  
-----X  
KAITLYN DIETRICK, Judge David R. Herndon

Plaintiff,

-against-

Civil Action No.:  
3:10-cv-12310-DRH-PMF

BAYER HEALTHCARE PHARMACEUTICALS, INC.,  
BAYER SCHERING PHARMA AG, BAYER CORPORATION,  
BAYER HEALTHCARE LLC, and BAYER AG

Defendants.

-----X  
**PLAINTIFFS' STEERING COMMITTEE'S MOTION FOR AUTHORITY TO  
PETITION THE FDA AND ITS ADVISORY COMMITTEES BY PRESENTING  
KEY "PROTECTED" DOCUMENTS CONCERNING PUBLIC HEALTH ISSUES  
REGARDING DROSPIRENONE-CONTAINING ORAL CONTRACEPTIVES**

The Plaintiffs' Steering Committee ("PSC") respectfully submits this *Motion for Authority to Petition the FDA and its Advisory Committees By Presenting Key "Protected" Documents Concerning Public Health Issues Regarding Drospirenone-Containing Oral Contraceptives* ("Motion") on behalf of Plaintiff Kaitlyn Dietrick. The PSC requests that this Court, pursuant to the United States Constitution, Amendment I, grant Plaintiff through her counsel and the PSC, the authority to petition the Food and Drug Administration ("FDA") and its Reproductive Health Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee (collectively the "Advisory Committees") for a redress of her grievances regarding the serious risks and side effects of drospirenone-containing oral contraceptives using documents currently designated as confidential under the Protective Order in the instant litigation.

### **INTRODUCTION**

The PSC files this Motion with supporting documents on behalf of Plaintiff Kaitlyn Dietrick in order to secure this Court's approval for her to use currently designated confidential documents to the FDA and its Advisory Committees at and leading up to the December 8, 2011 joint meeting addressing, *inter alia*, the safety of drospirenone-containing oral contraceptives. Defendants' position with respect to evidence that she wishes to present to the FDA materially undercuts her First Amendment right. Since approximately 1993, Defendants Bayer Healthcare Pharmaceuticals, Inc., Bayer Pharma AG (formerly known as Bayer Schering Pharma AG) and their related entities (collectively "Defendants" or "Bayer") have been submitting information to the FDA regarding drospirenone-containing oral contraceptives. However, there is evidence that the plaintiff desires to present to the FDA that will give that agency an opportunity it has not yet had to fully explore drospirenone-containing oral contraceptives' true propensity to cause venous

thromboemboli and other dangerous side effects. Plaintiff possesses unique and detailed knowledge regarding these risks including internal and candid memoranda of clinical trial data and adverse event data not shared with the FDA. Plaintiff further possesses information regarding potential conflicts of interest of persons currently sitting on the standing Advisory Committees. Thus, Plaintiff aims to exercise her right to petition the FDA by presenting this knowledge through a written submission to the FDA and the relevant Advisory Committees. However, because she is unable to present to the FDA the evidence of Bayer's wrongful conduct due to the broad confidentiality that Bayer has asserted in this litigation, her fundamental First Amendment right is rendered impotent. Without Plaintiff's assistance, the FDA may otherwise overlook significant safety information and public health risks. Central to the instant application, however, is that the claimed confidentiality shield should not obstruct her First Amendment right. Rather, it must yield to the Right to Petition, a right that is among the most fundamental to preserving and perpetuating our carefully crafted system of governance.

Accordingly, Plaintiff requests that this Court reject defendants' efforts to prevent the exercise of this important right, and de-designate certain documents currently claimed confidential under Case Management Order No. 7, *Order Concerning the Handling of Confidential Information* ("Protective Order"), attached as *Exhibit A*, and permit their submission and presentation to the FDA.

### **STATEMENT OF FACTS**

In 2009, Plaintiff Kaitlyn Dietrick was a healthy 17-year-old high-school student in Rochester, New York, who had always received "straight As" and participated in many sports and activities. Ms. Dietrick was first prescribed a drospirenone-containing oral contraceptive, Yaz, in March of 2009. Yaz was chosen over others because the prescriber understood that it

contained a lower dose of estrogen compared to other oral contraceptives, and thus believed it would be safer. Plaintiff consistently took Yaz as prescribed when, on the morning of December 24th, 2009, she began to feel an extreme pain in her chest. Plaintiff's mother and father took her to the hospital where she was diagnosed with a large pulmonary embolism completely obstructing much of her left pulmonary artery and multiple emboli in the right lung. She was hospitalized for six days and, due to her injuries, she has had to use blood thinners and has been forced to limit her physical activity. Plaintiff continues to suffer from the consequences of this event.

Due to the harm she has suffered, Plaintiff, by way of her right to petition and by and through her counsel, intends to present information to the FDA at the joint Advisory Committee meeting in order to reveal the shrouded evidence of the serious risks of drospirenone-containing oral contraceptives. Plaintiff, along with the other plaintiffs in this litigation, believes the Bayer submissions to have misconstrued the available data causing the FDA, and consequently physicians and the public, to overlook important safety information.

Plaintiff is one of the approximately 10,000 plaintiffs with cases filed in this Multi-District Litigation, a substantial number of injured women without taking into consideration the thousands more cases filed in state-court litigations in New Jersey, Pennsylvania, and California.<sup>1</sup> The drospirenone-containing oral contraceptives under review at the upcoming joint Advisory Committee meeting include Yasmin, Yaz, Ocella, Gianvi, Beyaz, Safyral, Syeda, Zarah, and Loryna.<sup>2</sup> Thus, the decision of the Advisory Committees and the FDA following the

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<sup>1</sup> The PSC acknowledges that these numbers encompass not just venous thromboembolism cases, but also other alleged injuries which include gallbladder disease, stroke, and heart-attack.

<sup>2</sup> See *Exhibit B*, FDA Drug Safety Communication: Safety review update on the possible increased risk of blood clots with birth control pills containing drospirenone (Sept. 26, 2011) (available online here: <http://www.fda.gov/drugs/drugsafety/ucm273021.htm>); *Exhibit C*, Federal Register, Vol. 76, No. 185, pp. 59143-44 (Sept. 23, 2011).

joint meeting will not only affect the women with cases filed in this litigation, but also millions of other women who take these many drugs, as well as the countless more women to whom Bayer will market these drugs in the future.

This FDA Advisory Committee meeting is especially significant because of Bayer's obvious long-term hopes for its drospirenone-containing oral contraceptive line. The Yaz, Yasmin line has in past years been the best-selling product line of Bayer's Pharmaceutical Division,<sup>3</sup> with \$1.11 billion in sales in 2010 alone.<sup>4</sup> According to Bayer's most-recent Annual Report, Yaz and Yasmin are considered some of their "most important patents."<sup>5</sup> Although Bayer has lost its patent in the United States for the formulation of these drugs, it maintains the patent on the dosage regimen for Yaz through 2014, and the production process for Yaz and Yasmin through 2025.<sup>6</sup> Consequently, the company will likely have some level of involvement or ownership in those drugs, whether the name-brand or generic versions, in the United States market for years to come. The decisions surrounding the labeling of these oral contraceptives will thus continue to affect millions of women. Further, Bayer's new drospirenone-containing oral contraceptives Beyaz (which has the same formulation as Yaz, but with the addition of levomefolate calcium) and Safyral (which has the same formulation as Yasmin, but with the addition of levomefolate calcium) were approved by the FDA in late 2010.<sup>7</sup> If the safety of these medications is not correctly analyzed at this time, the drospirenone-containing oral contraceptive line could continue to grow without proper warning information, to the detriment of an immeasurable number of women, and their families. Such a stunningly serious backdrop starkly

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<sup>3</sup> See Bayer's 2010 Annual Report, p. 5 (published February 2011) (available online here: <http://www.annualreport2010.bayer.com/en/Bayer-Annual-Report-2010.pdf>)

<sup>4</sup> *Id.* at p. 60.

<sup>5</sup> *Id.* at p. 201.

<sup>6</sup> *Id.*

<sup>7</sup> See *Exhibit D*, 9/24/2010 FDA Approval Letter for Beyaz, and *Exhibit E*, 12/16/2010 FDA Approval Letter for Safyral.

illustrates the import of Ms. Dietrick's First Amendment right to petition her government. Whatever protections these Defendants, including the foreign Defendants, claim under the laws of the United States, those protections can not undermine the right provided to Ms. Dietrick 220 years ago in the First Amendment to our Constitution.

The Advisory Committees will be meeting on December 8, 2011 to discuss safety issues regarding drospirenone-containing oral contraceptives, used by woman all over the world. Particular safety issues to be discussed are "benefits and risks of drospirenone-containing oral contraceptives in light of the emerging safety concern that the risk of venous thromboembolism (blood clots that can break loose and move within the circulatory system) associated with the use of these products may be higher compared to oral contraceptives that contain the progestin, levonorgestrel."<sup>8</sup> The participation by Ms. Dietrick and others like her in this process was specifically invited by the FDA and indeed the right to do so is mandated by regulation. *See* Administrative Procedure Act, 5 U.S.C. § 553(e); 21 C.F.R § 10.30 (2011); 5 U.S.C. App. 2, § 10(3). Interested persons are permitted to present data, information, or views on issues pending before the committee, via oral presentation or written submission.<sup>9</sup> Plaintiff, through her attorneys, would like to take this opportunity to petition the FDA with material information in order to assist them in their regulatory mandate.

## **ARGUMENT**

### **I. Plaintiff's Constitutional and Statutory Right to Petition the FDA.**

The First Amendment of the United States Constitution permits a citizen of this country "to petition the Government for a redress of grievances." U.S. CONST. amend. I. This doctrine applies to petitioning activities directed at legislative, administrative, or judicial branches of

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<sup>8</sup> *Exhibit C*, Federal Register, Vol. 76, No. 185, p. 59143.

<sup>9</sup> *Id.* at 59144.

government. *California Motor Transp. Co. v. Trucking Unlimited*, 404 U.S. 508, 510 (1972).

The right to petition allows citizens to express their ideas, hopes, and concerns to their government and their elected representatives. *Borough of Duryea, Pa. v. Guarnieri*, 131 S. Ct.

2488, 2495 (2011). The Supreme Court has recently observed that:

Petitions to the government assume an added dimension when they seek to advance political, social, or other ideas of interest to the community as a whole. Petition, as a word, a concept, and an essential safeguard of freedom, is of ancient significance in the English law and the Anglo–American legal tradition. See, e.g., 1 W. Blackstone, *Commentaries* \*143. The right to petition applied to petitions from nobles to the King, from Parliament to the King, and from the people to the Parliament, and it concerned both discrete, personal injuries and great matters of state.

*Id.* at 2498. The Court also discussed how petitions to courts and similar bodies can also address matters of public import, noting that: “[I]itigation on matters of public concern may facilitate the informed public participation that is a cornerstone of democratic society. It also allows individuals to pursue desired ends by direct appeal to government officials charged with applying the law.” *Id.* at 2500. Here, a significant if not primary aspect of Ms. Dietrick and her family’s motivation in bringing her claim was to raise awareness surrounding this important safety issue. Now aware of this important regulatory event that can affect millions of young women and girls like her, Ms. Dietrick wants, and our Constitution entitles her, to take this step and petition the FDA and its Advisory Committees with information she and her attorneys now possess.

Plaintiff’s First Amendment right to petition the FDA and address her grievances is specifically buttressed in the Administrative Procedure Act, 5 U.S.C. § 553(e). The codification requires every agency to “give an interested person the right to petition for the issuance, amendment, or repeal of a rule,” and the FDA has issued the petition procedures at 21 C.F.R. § 10.30 (2011) and 5 U.S.C. App. 2, § 10(3) (“Interested persons shall be permitted to attend,

appear before, or file statements with any advisory committee, subject to such reasonable rules or regulations as the Administrator may prescribe”).

The U.S. Supreme Court has recognized the right to petition as one of “the most precious of the liberties safeguarded by the Bill of Rights,” *Mine Workers v. Illinois Bar Ass’n*, 389 U.S. 217, 222 (1967); *see also BE & K Constr. Co. v. NLRB*, 536 U.S. 516, 524 (2002). Here, Plaintiff must substantially abandon this liberty because the defendants refuse to permit the disclosure of certain information. The irony of this situation is extraordinary. The Bayer defendants, including the foreign corporation, have total and unfettered access to the Advisory Committees and the FDA. They can and will submit massive briefing and will have a multi-hour, carefully choreographed presentation to the Advisory Committees. Yet, an individual citizen of the United States who, no one seriously denies, was almost killed by a drosiprenone medication, is barred by those foreign and domestic corporations from presenting the evidence she has chosen in opposition. Under these circumstances, the First Amendment dissolves such irony and permits disclosure and free discourse.

In the case of *Chicago Council of Lawyers v. Bauer*, 522 F.2d 242 (7th Cir. 1975), *cert. denied*, 427 U.S. 912 (1976), the Court of Appeals struck down a “no-comment” rule in the District Court for the Northern District of Illinois that plaintiff lawyers claimed deprived attorneys of their free speech rights under the First Amendment to make extrajudicial public comments on pending litigation. In evaluating the no-comment rule specifically in the context of civil actions, *id.* at 257-59, the Court noted that:

Civil litigation in general often exposes the need for governmental action or correction. Such revelations should not be kept from the public. Yet it is normally only the attorney who will have this knowledge or realize its significance. Sometimes a class of poor or powerless citizens challenges, by way of a civil suit, actions taken by our established private or semi-private institutions or governmental entities. Often non-lawyers can adequately comment publicly on

behalf of these institutions or governmental entities. The lawyer representing the class plaintiffs may be the only articulate voice for that side of the case. Therefore, we should be extremely skeptical about any rule that silences that voice.

*Id.* at 258. This reasoning squarely applies here. Similarly, in *Jepson, Inc. v. Makita Electric Works, Ltd.*, 30 F. 3d 854 (7th Cir. 1994), the Seventh Circuit noted that: “Absent a protective order, parties to a law suit may disseminate materials obtained during discovery as they see fit.” Citing *Oklahoma Hosp. Ass’n v. Oklahoma Pub. Co.*, 748 F.2d 1421, 1424 (10th Cir.1984), *cert. denied*, 473 U.S. 905, 105 S.Ct. 3528, 87 L.Ed.2d 652 (1985). Although other another aspect of the *Jepson* rationale has since been overturned (*see, e.g., Bond v. Utreras*, 585 F.3d 1061 (7th Cir. 2009)), this notion was recently cited by *Salmeron v. Enterprise Recovery Sys., Inc.*, 579 F.3d 787, 795 (7th Cir. 2009). There is evidence known to Ms. Dietrick and her attorneys that she wants to share with the FDA and Defendants should not be permitted to silence her.

## **II. This Court Should De-Designate the Documents at Issue Upon the Grounds That They are Inappropriately Designated Confidential.**

The documents that Plaintiff would like to present to Advisory Committees are part of a massive production of approximately 3.65 million documents many of which have been marked “confidential” or “highly confidential” by Defendants. Plaintiff respectfully contends that Defendants’ designation of so many documents as confidential is a clear misuse of the protective order, and such misuse should not bar Plaintiff from exercising her right to petition to the FDA. Plaintiff has conferred with the Defendants and defense counsel has informed the PSC that they will not de-designate the documents at issue on this motion.<sup>10</sup>

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<sup>10</sup> Plaintiffs’ counsel e-mailed defense counsel regarding the first set of documents on October 7, 2011 and received a response on October 21, 2011. Defendants granted our request to de-designate 12 documents (attached hereto as *Exhibits F through Q*), and further pointed out that 13 of the documents we raised were not designated by Bayer as confidential and thus were not an issue. They denied our request with regard 71 documents and deposition testimony. The PSC has submitted a second set of documents to Defendants, based on information recently discovered by Plaintiffs’ Counsel. The PSC would like to try to continue to work with Defendants on reaching a solution for all documents, but having no guarantees, and given the immediacy of the December 8th hearing, we

Plaintiff would like to submit to and analyze for the FDA the following documents, but since they are currently designated as confidential she can not discuss in this brief why they are important:

- BHCPYAZ000016464 (1 page)
- BHCPYAZ000016465 (1 page)
- BHCPYAZ000017204 (1 pages)
- BHCPYAZ001015319 (33 pages)
- BHCPYAZ003608240 (94 pages)
- BHCPYAZ005213686 (350 pages)
- BHCPYAZ005894785 (184 pages)
- BHCPYAZ006641253 (25 pages)
- BHCPYAZ013302472 (4 pages)
- BHCPYAZ013313889 (30 pages)
- BHCPYAZ013670071 (74 pages)
- BHCPYAZ015775289 (21 pages)
- BHCPYAZ016445391 (8 pages)
- BHCPYAZ030094603 (12 pages)
- BSPYAZ000034452 (10 pages)
- BSPYAZ000334520 (1 page)
- BSPYAZ004071247 (12 pages)
- BSPYAZ004074726 (32 pages)
- BSPYAZ006191224 (6 pages)
- BSPYAZ007629931 (9 pages)
- BSPYAZ010646856 (25 pages)
- BSPYAZ013467039 (3 pages)
- BSPYAZ013467045 (3 pages)
- BSPYAZ016107358 (2 pages)
- BSPYAZ020389673 (24 pages)
- BSPYAZ020405494 (3 pages)
- BSPYAZ020413622 (3 pages)
- BSPYAZ020414848 (3 pages)
- BSPYAZ020429478 (31 pages)
- BHCPYAZ000673420 (4 pages)
- BHCPYAZ030096499 (3 pages)
- BSPYAZ001855146 (42 pages)
- BSPYAZ001859323 (5 pages)
- BSPYAZ002018263 (2 pages)
- BSPYAZ003040490 (5 pages)
- BSPYAZ003910074 (4 pages)

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have no choice but to file the motion. If Defendants ultimately agrees to lift the claims of confidentiality, then this motion may become mooted, but as of now, the documents are still protected and protection still needs to be lifted.

- BSPYAZ004005438 (9 pages)
- BSPYAZ010659932 (3 pages)
- BSPYAZ010659953 (1 page)
- BSPYAZ010660038 (4 pages)
- BSPYAZ011360078 (143 pages)
- BSPYAZ012630915 (7 pages)
- BSPYAZ020269993 (4 pages)

These documents are not presently being attached to this publicly filed version of this motion. Further, the detailed and specific reasons why these documents are not deserving of confidential treatment cannot fully be explained herein as such explanation would necessarily require a discussion of the currently confidential part of the documents. However, the documents can be presented *in camera* or filed under seal, if permitted.

Plaintiffs stipulated to the subject Protective Order on the condition that the documents designated as protected were designated in accordance with Fed. R. Civ. P. 26(c), which allows for a protective order *only* “for good cause” in order “to protect a party or person from annoyance, embarrassment, oppression, or undue burden or expense” or to protect “trade secret or other confidential research, development, or commercial information.” “Good cause” is the basis for the protection, and a blanket protective order, like the one entered here, temporarily postpones the good cause showing until a party or intervenor challenges the continued confidential treatment of particular documents. Defendants have broadly designated millions of pages of documents as confidential without a legitimate reason. While it may have made logistical sense for Defendants to produce documents in this manner in order to expedite discovery, now there is a concrete and urgent need to reevaluate these designations. Defendants must first show “for each particular document it seeks to protect ... that specific prejudice or harm will result if no protective order is granted.” *Foltz v. State Farm Mut. Aut. Ins. Co.*, 331 F.3d 1122, 1130 (9th Cir. 2003). “A party who has never made a ‘good cause’ showing under

Rule 26(c) justifying initial protection of disputed documents may not rely solely on the protective order to justify refusal when there is a reasonable request for disclosure.” *Verizon California, Inc. v. Ronald A. Katz Tech. Licensing, L.P.*, 214 F.R.D. 583, 586 (C.D.Cal.2003) (citing *Beckman*, 966 F.2d at 476; *Olympic Ref. Co. v. Carter*, 332 F.2d 260, 264-65 (9th Cir. 1964)); *see also Foltz*, 331 F.3d at 1138. Thus, defendants bear the burden to demonstrate that protection is warranted under Rule 26(c).

Although many documents designated by Defendants contain information adverse to the Defendants’ interests in this litigation and perhaps even their public image, such reasons clearly do not satisfy the requirements for protected status under the Fed. R. Civ. P. 26(c) standard. As noted by the Seventh Circuit in *Gotham Holdings, LP v. Health Grades, Inc.*, 580 F.3d 664, 665 (7th Cir. 2009): “Indeed, we have stated more broadly that a person’s desire for confidentiality is not honored in litigation. Trade secrets, privileges, and statutes or rules requiring confidentiality must be respected, *see Fed.R.Civ.P. 45(c)(3)(A)(iii)*, but litigants’ preference for secrecy does not create a legal bar to disclosure.” *Citing Baxter International, Inc. v. Abbott Laboratories*, 297 F.3d 544 (7th Cir. 2002); *United States v. Foster*, 564 F.3d 852 (7th Cir. 2009) (Easterbrook, C.J., in chambers).

Plaintiff expects Defendants to argue that many of the documents are covered by the trade secret privilege. In the case of trade secrets, however, “[t]here is no absolute privilege [against disclosure] for trade secrets and similar confidential information.” *DDS, Inc. v. Lucas Aerospace Power Transmission Corp.*, 182 F.R.D. 1, 4 (N.D.N.Y. 1998) quoting *Federal Open Mkt. Comm. of Fed. Reserve Sys. V. Merrill*, 443 U.S. 340, 362 (1979). Courts should only seal the records if the documents are “legitimate trade secrets.” *Brown & Williamson Tobacco Corp.*, 710 F.2d 1165, 1180 (6th Cir. 1983), *cert. denied*, 465 U.S. 1100. “Simply showing that the

information would harm the company's reputation is not sufficient to overcome the strong common law presumption in favor of public access to court proceedings and records.” *Id.* at 1179. “A party resisting discovery must show that the information is a trade secret and disclosure might be harmful.” *DDS, Inc.*, 182 F.R.D. at 4. “The harm must be ‘clearly defined and very serious...’” *Id.*

Furthermore, it has been found that stale documents do not maintain their commercially sensitive value. *Zenith Radio Corp. v. Matsushita Electric Industrial Co.*, 529 F. Supp. 866, 891-892 (E.D. Pa. 1981) (“An attempt to show that disclosure will indeed work a competitive disadvantage might be undermined if the information sought to be protected were stale.”) While it is difficult to place temporal boundaries that would define whether a document is stale, *Zenith* found that cases have noted that information beyond three years old loses its commercial viability. In *Vollert v. Summa Corp.*, 389 F. Supp. 1348 (D. Haw. 1975) and *Hecht v. Pro-Footbal, Inc.*, 46 F.R.D. 605 (D.D.C. 1969), “information up to three years old was held entitled to confidentiality.” 529 F. Supp. at 891. But in *United States v. International Business Mach. Corp.*, 67 F.R.D. 40 (S.D.N.Y. 1975), “information three to fifteen years old was held not entitled to protection because . . . it revealed little . . . about the contemporary operations of the party resisting disclosure.” *Id.* Similarly, *United States v. Lever Bros. Co.*, “held that information three to eight years old should not be protected.” *Id.*

Designation of a document as a “protected document” under the Protective Order does not signify that Plaintiff agreed that the designated disclosure constituted confidential information, nor did she surrender her right to contest the designations made by Bayer. As noted in paragraph I.F.: “The Protective Order does not confer blanket protections on all disclosures or responses to discovery and the protection it affords extends only to the specific

information or items that are entitled to protection under the applicable legal principles for treatment as confidential.” Many documents, including the safety information buried in the discovery, are not and never were entitled to protection under applicable legal principles. Even in the absence of a question concerning Plaintiff’s exercise of her First Amendment rights, they should therefore be “de-designated”. Certainly in the face of Plaintiff’s First Amendment rights, the documents should be stripped of their inappropriate classification and their use permitted to petition the FDA for regulatory action to properly characterize the risk that drospirenone-containing medications present.

As Hon. Jack Weinstein recognized in the *Zyprexa* litigation: “Public access is ... advisable because this litigation involves issues of great public interest, the health of hundreds of thousands of people, [and] fundamental questions about our system of approval and monitoring of pharmaceutical products...[P]ublic disclosure, congruent with our long tradition of open courts, is desirable.” *In re Zyprexa Prods. Liab. Litig.*, 263 F.R.D. 69, 208-09 (E.D.N.Y. 2007).

In sum, this Court should not permit the Protective Order to prevent Plaintiff from meaningfully petitioning the FDA. The information Plaintiff aims to interpret and present can be de-designated for various reasons and is integral to Plaintiff’s right to petition the FDA regarding her grievances concerning drospirenone-containing oral contraceptives.

### **III. This Court Should Further De-Designate Documents Regarding Potential Conflicts of Interest of Standing Advisory Committee Members.**

To assist in its mission to protect and promote public health, the FDA uses a number of committees and panels to obtain independent expert advice. One of the two committees being called to the joint meeting on December 8, 2011, the Reproductive Health Drugs Advisory Committee, is responsible for reviewing and evaluating data on the safety and effectiveness of marketed and investigational human drugs for use in the practice of obstetrics, gynecology, and

related specialties, and makes appropriate recommendations to the Commissioner of Food and Drugs.<sup>11</sup> The other committee, the Drug Safety and Risk Management Advisory Committee, is responsible for advising the Commissioner of Food and Drugs on drug risks, after reviewing safety and efficacy information, and giving recommendations on how to manage and communicate these risks.<sup>12</sup> The Drug Safety and Risk Management Advisory Committee also conducts quantitative evaluation of spontaneous reports for drugs for human use and for any other product for which the Food and Drug Administration has regulatory responsibility.<sup>13</sup>

Each of the two committees shall consist of a core of 13 voting members, including the Chair.<sup>14</sup> The standing members of these Advisory Committees are posted on the FDA's website.<sup>15</sup> Plaintiff's counsel reviewed the lists and compared the members' names to information obtained in this litigation and found documents showing that various members have had involvement with Bayer. Plaintiff would like to descriptively submit to FDA the following documents:

- BHCPYAZ006431634 (26 pages)
- BHCPYAZ008161471 (253 pages)

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<sup>11</sup> See Food and Drug Administration, "Reproductive Health Drugs Advisory Committee", at <http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/ReproductiveHealthDrugsAdvisoryCommittee>.

<sup>12</sup> See Food and Drug Administration, "Drug Safety and Risk Management Advisory Committee", at <http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/DrugSafetyandRiskManagementAdvisoryCommittee>.

<sup>13</sup> *Id.*

<sup>14</sup> See Food and Drug Administration, "Drug Safety and Risk Management Advisory Committee Roster", at <http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/DrugSafetyandRiskManagementAdvisoryCommittee/ucm094892.htm>; Food and Drug Administration, "Reproductive Health Drugs Advisory Committee Roster", at <http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/ReproductiveHealthDrugsAdvisoryCommittee/ucm107573.htm>.

<sup>15</sup> Notably, according to the most recently updated information posted on the Advisory Committees website, the Drug Safety and Risk Management Advisory Committee has one vacancy, and the Reproductive Health Drugs Advisory Committee has six vacancies, which includes the Chair. *Id.* The FDA may be filling these vacancies in the days leading up to the December 8, 2011 joint meeting. Further, in the past, the FDA has invited temporary members to sit on an Advisory Committee for a particular meeting, and thus additional members may be announced in this context. Thus, if the newly announced members appear to have potential conflicts based on documents designated as confidential in this litigation, the PSC may need to petition the Court again in the future if the Defendants do not timely agree to de-designate the documents at issue.

- BHCPYAZ009140241 (10 pages)
- BHCPYAZ016683426 (18 pages)
- BHCPYAZ016864902 (28 pages)
- BHCPYAZ019250794 (15 pages)
- BHCPYAZ019994435 (161 pages)
- BHCPYAZ020016400 (161 pages)
- BHCPYAZ024067148 (1 page)
- BHCPYAZ032917013 (2 pages)
- BHCPYAZ032986428 (13 pages)
- BHCPYAZ033443504 (39 pages)
- BSPYAZ002528290 (28 pages)
- BSPYAZ020787403 (14 pages)
- BSPYAZ021432381 (2 pages)

Given the import of this meeting and the Advisory Committee's recommendations to the FDA regarding the safety and labeling of these drugs, it is essential that the FDA be advised of these potential conflicts so that any possible bias can be avoided. Defendants' claims of confidentiality for any of these documents is outweighed by the public interest in assuring that the Advisory Committees are free from bias.

**IV. Plaintiff Should be Permitted to Petition the FDA Simply Due to the Importance of the Information to Public Safety, and the Diminished Ability of the FDA to Access and Process this Information.**

In holding that failure-to-warn claims do not conflict with federal law, the U.S. Supreme Court has noted that "[t]he FDA has limited resources to monitor the 11,000 drugs on the market." *Wyeth v. Levine*, 129 S. Ct. 1187, 1202 (2009) (pointing out that recent studies have concluded that the FDA's budget and staff are inadequate to meet its large responsibilities). As in the instant case, "manufacturers have superior access to information about their drugs, especially in the postmarketing phase as new risks emerge," *id.*, and Plaintiff aims to assist the FDA in protecting the public by sharing the superior access to information she acquired by way of the instant law suit. Notably, the FDA has itself found that "product liability plays an important role in consumer protection" and Plaintiff intends to air her grievances to the FDA by

providing her interpretation of the data obtained in this litigation. 59 Fed. Reg. 3948 (1994); *see also Wyeth*, 129 S. Ct. at 1202, n.10.

The FDA “has long been hamstrung by resource limitations and gaps in the agency's statutory authority.” David A. Kessler & David C. Vladeck, *A Critical Examination of the FDA's Efforts to Preempt Failure-to-Warn Claims*, 96 GEO. L.J. 461, 483 (2008) (article cited by the Supreme Court in their analysis of the FDA's capabilities. *Wyeth*, 129 S. Ct. at 1202-03, n.12). The agency regulates products that amount to one-quarter of the consumer spending in the United States, but only has approximately 9,000 employees nationwide. Kessler, *supra*, at 484. In fact, FDA doctors and scientists believe that the agency lacks the resources needed to accomplish its complex mission to protect the public health and monitor the safety of drugs once they are on the market. *Id.* at 484-485.

Not only is the FDA unable to uncover all of the risk data in the documents provided to it by pharmaceutical companies, but companies also do not provide all of the risk information that they possess. *Id.* at 491-92. Companies are not under an obligation to provide the agency with records of internal discussions or evaluations by company physicians and scientists. *Id.* at 491. Furthermore, once a drug is approved, companies have no obligation to provide the FDA with company evaluations of a drug's performance in the market or the drug's safety profile. *Id.* at 491-92.

Information-gathering tools available in litigation are much more extensive than the FDA's, especially considering lawyers may subpoena relevant information from any source. *Id.* at 492. This is shown by the affect past litigations have had on the FDA's safety monitoring and decisions. *Id.* For example, litigation uncovered information that led the FDA to include warnings for heart attack and stroke on the labels of Vioxx and Celebrex. *Id.* Lawyers in those

cases uncovered internal documents and unpublished data that were not provided to the FDA. *Id.* at 492-93. Litigation also uncovered the risks associated with the sleeping medication Halcion, the arthritis medication Zomax, and the weight loss pill ephedra causing the FDA to take those drugs off the market. *Id.* at 493. For additional examples, *see also*, Teresa Curtin and Ellen Relkin, *Preamble Preemption And The Challenged Role Of Failure To Warn And Defective Design Pharmaceutical Cases In Revealing Scientific Fraud, Marketing Mischief, And Conflicts Of Interest*, 35 HOFSTRA L. REV. 1773, 1787 (Summer 2007).

Aptly noted by Kessler and Vladeck, the FDA is “a small ‘David’ facing dozens of ‘Goliaths’” and no matter what legislation is passed, the pharmaceutical companies will always have vastly greater resources to monitor their own products than the FDA has. *Id.* at 495. Thus, the benefits of information collection in litigation should not be ignored. *Id.* Here, Plaintiff has evidence of “newly acquired information” (which includes “new analyses of previously submitted data”), *Wyeth*, 129 S. Ct. at 1197 (citing 73 Fed. Reg. 49604), regarding drospirenone-containing oral contraceptives and, therefore, Plaintiff should be allowed to petition the FDA by presenting this information to FDA and requesting that it be presented to the Advisory Committees before they make important safety and labeling decisions.

Plaintiff, by her counsel and experts, is in a unique position in that she has detailed knowledge regarding the safety of drospirenone-containing oral contraceptives, as she has been able to access the documents and data that the FDA has accessed and more, and has had the time and resources to focus on the specific issue of venous thromboemboli. Since Plaintiff’s counsel and experts received the materials, they knew what they were looking for, evidence of the increased risk of venous thromboembolism in drospirenone-containing oral contraceptives, and found it, a goal the FDA did not originally have and may be unable to fully meet. Therefore,

Plaintiff has done detailed work that the FDA has not been able to do, and should be able to share this as a benefit to the FDA, especially as this is the specific issue being addressed at the upcoming meeting.

In sum, the FDA has not been given the tools necessary to do its job, and therefore when it first approved drospirenone-containing oral contraceptives, it did not require Bayer to include a label that adequately warned Plaintiff of the increased risk of venous thromboemboli. Plaintiff intends to exercise her right to petition, a right the U.S. Supreme Court has found is implied by “[t]he very idea of a government, republican in form,” *United States v. Cruikshank*, 92 U.S. 542, 552 (1876), for a redress of her grievance regarding this to-date inadequate review and labeling of drospirenone-containing oral contraceptives. This Court should grant Plaintiff’s Motion and allow her to petition the FDA and offer information to assist in the review and labeling decisions for new indications that will affect the health of literally millions of women.

**V. Alternatively, Plaintiff Requests Permission to Refer to “Confidential” Information Already Within the FDA’s Possession, In Order to Direct the FDA to Areas of Concern.**

If the Court denies Plaintiff’s request with regard to some or all of the documents listed *supra*, Plaintiff requests that the Court alternatively allow her to refer to documents and information her counsel has obtained through this litigation that are already within the possession of the FDA, in order to direct the FDA and Advisory Committees’ attention to particular areas of concern. For instance, as mentioned above, Bayer has been submitting materials by way of its New Drug Applications and supplemental and supporting materials. These materials contain studies, case reports, and other such information and data that Plaintiff’s counsel and experts have re-analyzed, coming to conclusions different from those reached by Bayer. Therefore, if the Court declines to grant Plaintiff’s requests for de-designation and use of documents with the

FDA, Plaintiff respectfully asks the Court to allow her to submit briefing to the Advisory Committee that refers the committee members and FDA to information to which they already have access and to describe the opinions and analysis Plaintiff's experts have offered in this case.

**CONCLUSION**

For the reasons stated herein, it is respectfully requested that this Court grant Plaintiff's motion in its entirety, together with such other relief as this Court deems just and proper.

Dated: October 27, 2011

**PLAINTIFFS' STEERING COMMITTEE**

By: /s/ Roger C. Denton

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**CERTIFICATE OF SERVICE**

I hereby certify that the foregoing was electronically filed on October 27, 2011 with the Clerk of Court using the CM/ECF system, and emailed to all Plaintiffs' counsel.

/s/ Roger C. Denton